

AMENDMENTS

In the Claims:

Please amend claims 1, 16, 25, 26 and 45-47, add new claims 48 and 49, and cancel claim 44, as follows:

1. (currently amended) A process for obtaining a HMG-CoA reductase inhibitor comprising one of the steps in the process of the purification of a crude HMG-CoA reductase inhibitor which includes displacement chromatography and involves using a displacer [~~displacers~~] for displacing the HMG-CoA reductase inhibitor.
2. (previously amended) A process according to claim 1, wherein the HMG-CoA reductase inhibitor is selected from the group consisting of mevastatin, pravastatin, lovastatin, simvastatin, fluvastatin or atorvastatin.
3. (previously amended) A process according to claim 1, wherein the HMG-CoA reductase inhibitor has a lactone form or is in the form of the acid or the salt thereof.
4. (previously amended) A process according to claim 1, wherein the displacement chromatography includes the following steps:
 - a) conditioning a chromatography column with a mobile phase;
 - b) feeding the HMG-CoA reductase inhibitor dissolved in the mobile phase onto the chromatography column;
 - c) introducing the displacer for displacing the HMG-CoA reductase inhibitor from the column; and
 - d) obtaining the purified HMG-CoA reductase inhibitor.

5. (previously amended) A process according to claim 4, characterized in that the purified HMG-CoA reductase inhibitor is obtained by

- d1) collecting fractions; and
- d2) analyzing the fractions with analytical HPLC and pooling the fractions depending on the quality of purity.

6. (previously amended) A process according to claim 4, wherein the displacement chromatography further includes:

- e) regenerating the chromatography column by washing the column with alcohol/water mixture to elute the displacer.

7. (previously amended) A process according to claim 4, wherein the mobile phase is selected from the group of solvents consisting of water, acetonitrile/water solutions, aqueous solutions of lower alcohols, and buffered dilute solutions of organic, halogenated organic or inorganic acids with alkaline metal cations, with ammonia or with amines.

8. (previously amended) A process according to claim 4, wherein the mobile phase is selected from the group of solvents consisting of water, acetonitrile/water solutions and aqueous solutions of lower alcohols.

9. (previously amended) A process according to claim 4, wherein the pH of the mobile phase used is between 4.5 and 10.5.

10. (previously amended) A process according to claim 9, wherein the pH of the mobile phase used is between 6.5 and 8.

11. (previously amended) A process according to claim 10, wherein the pH of the mobile phase used is 7.
12. (previously amended) A process according to claim 4, wherein the flow rate of the mobile phase through the chromatographic column is between 1.5 and 30 mL/ (min cm²).
13. (previously amended) A process according to claim 4, wherein the flow rate of the mobile phase/displacer mixture through the chromatographic column is between 3 and 15 mL/ (min cm²).
14. (previously amended) A process according to claim 6, wherein the stationary phase is regenerated with 20 to 100% aqueous solution of lower alcohols after completed chromatography.
15. (previously amended) A process according to claim 4, wherein the stationary phase is a reverse phase.
16. (currently amended) [R] A process according to claim 15, wherein the stationary phase is a natural reverse phase including silica gel with alkyl chains of different lengths.
17. (previously amended) A process according to claim 15, wherein the stationary phase is either C-18 or C-8.
18. (previously amended) A process according to claim 15, wherein the stationary phase is a synthetic cross-linked polymer matrix .

19. (previously amended) A process according to claim 18, wherein the cross-linked polymer matrix is a copolymer of styrene and divinylbenzene.

20. (previously amended) A process according to claim 4, wherein the particle size of the stationary phase is between 3 and 20 μm .

21. (previously amended) A process according to claim 20, wherein the particle size of the stationary phase is between 7 and 15 μm .

22. (previously amended) A process according to claim 4, wherein the displacer is selected from the group consisting of long chain alcohols, long chain carboxylic acids, long chain alkyl ammonium salts, aromatic dicarboxylic acid esters, oxo- and dioxo-alcohols, polyalkylene polyglycol ethers and polyaryl or polyalkylene polyaryl ethers.

23. (previously amended) A process according to claim 4, wherein the concentration of the displacer in the mobile phase is between 1 and 35%.

24. (previously amended) A process according to claim 23, wherein the concentration of the displacer in the mobile phase is between 2 and 20%.

25. (currently amended) A process according to claim 4 [4], wherein the HMG-CoA reductase inhibitor obtained by the process has HPLC purity exceeding 99.7%.

26. (currently amended) A process according to claim 4 [2] wherein:

[~~(a)~~] the HMG reductase inhibitor has a lactone form or is in the form of the acid or the salt thereof;

~~[~~(b)~~ the displacement chromatography includes:~~

- ~~(i) conditioning a chromatography column with a mobile phase;~~
- ~~(ii) feeding the HMG CoA reductase inhibitor dissolved in the mobile phase onto the chromatography column;~~
- ~~(iii) introducing the displacer for displacing the HMG CoA reductase inhibitor from the column; and~~

~~(iv)] wherein the purified HMG-CoA reductase inhibitor is obtained by collecting HMG-CoA reductase inhibitor fractions from the stationary phase and pooling the fractions depending on the quality of purity;~~
wherein the mobile phase is any one of water, an acetonitrile/water solution or an aqueous solution of lower alcohols;

wherein the pH of the mobile phase used is between 4.5 and 10.5;
wherein the flow rate of the mobile phase through the chromatographic column is between 1.5 and 30 ml/(min cm²) ;

wherein the stationary phase is either C-18 or C-8 and the cross-linked polymer matrix of the stationary phase is a copolymer of styrene and divinylbenzene;

wherein the particle size of the stationary phase is between 3 and 20 μ m; and
wherein the displacer is selected from the group consisting of long chain alcohols, long chain carboxylic acids, long chain alkyl ammonium salts, aromatic dicarboxylic acid esters, oxo- and dioxo-alcohols, polyalkylene polyglycol ethers and polyaryl or polyalkylene polyaryl ethers and wherein the concentration of the displacer in the mobile phase is between 1 and 35%.

27. (previously added) A process according to claim 26 wherein the HMG-CoA reductase inhibitor obtained by the process has HPLC purity exceeding 99.7%.

28. (previously added) An HMG-CoA reductase inhibitor obtained by purifying crude HMG-CoA reductase inhibitor by means of a purification process which is displacement chromatography resulting in an HPLC-purity exceeding 99.7%.

29. (previously added) An HMG-CoA reductase inhibitor according to claim 28, characterized in that the HMG-CoA reductase inhibitor is selected from the group consisting of lovastatin, simvastatin, pravastatin, atorvastatin, mevastatin, and fluvastatin.

30. (previously added) An HMG-CoA reductase inhibitor according to claim 29, characterized in that the selected HMG-CoA reductase inhibitor is lovastatin, simvastatin, or pravastatin.

31. (previously added) An HMG-CoA reductase inhibitor according to claim 28, characterized in that the selected HMG-CoA reductase inhibitor is in a lactone form or in the form of an acid or a salt.

32. (previously added) An HMG-CoA reductase inhibitor with an HPLC purity exceeding 99.7% obtained by purifying a crude HMG-CoA reductase inhibitor by means of a purification process which is the displacement chromatography of claim 4.

33. (previously added) An HMG-CoA reductase inhibitor of claim 32, characterized in that the HMG-CoA reductase inhibitor is selected from the group consisting of lovastatin, simvastatin, pravastatin, atorvastatin, mevastatin and fluvastatin.

34. (previously added) An HMG-CoA reductase inhibitor of claim 33, characterized in that the selected HMG-CoA reductase inhibitor is lovastatin, simvastatin, or pravastatin.

35. (previously added) An HMG-CoA reductase inhibitor of claim 32, characterized in that the selected HMG-CoA reductase inhibitor is in a lactone form or in the form of an acid or a salt.

36. (previously added) An HMG-CoA reductase inhibitor with an HPLC purity exceeding 99.7% obtained by purifying a crude HMG-CoA reductase inhibitor by means of a purification process which is the displacement chromatography of claim 5.

37. (previously added) An HMG-CoA reductase inhibitor of claim 36, characterized in that the HMG-CoA reductase inhibitor is selected from the group consisting of lovastatin, simvastatin, pravastatin, atorvastatin, mevastatin and fluvastatin.

38. (previously added) An HMG-CoA reductase inhibitor of claim 37, characterized in that the selected HMG-CoA reductase inhibitor is lovastatin, simvastatin, or pravastatin.

39. (previously added) An HMG-CoA reductase inhibitor of claim 36, characterized in that the selected HMG-CoA reductase inhibitor is in a lactone form or in the form of an acid or a salt.

40. (previously added) An HMG-CoA reductase inhibitor with an HPLC purity exceeding 99.7% obtained by purifying a crude HMG-CoA reductase inhibitor by means of a purification process which is the displacement chromatography of claim 26.

41. (previously added) An HMG-CoA reductase inhibitor of claim 40, characterized in that the HMG-CoA reductase inhibitor is selected from the group consisting of lovastatin, simvastatin, pravastatin, atorvastatin, mevastatin and fluvastatin.

42. (previously added) An HMG-CoA reductase inhibitor of claim 41, characterized in that the selected HMG-CoA reductase inhibitor is lovastatin, simvastatin, or pravastatin.

43. (previously added) An HMG-CoA reductase inhibitor of claim 40, characterized in that the selected HMG-CoA reductase inhibitor is in a lactone form or in the form of an acid or a salt.

44. (cancelled) ~~A process for obtaining an HMG-CoA reductase inhibitor, characterized in that the process is a purification of a crude HMG-CoA reductase inhibitor by displacement chromatography and involves using a displacer for displacing the HMG-CoA reductase inhibitor, comprising the steps of:~~

- ~~a) conditioning a chromatography column with a mobile phase;~~
- ~~b) feeding the crude HMG-CoA reductase inhibitor dissolved in the mobile phase onto the chromatography column;~~
- ~~c) introducing the displacer for displacing the HMG-CoA reductase inhibitor from the column; and~~
- ~~d) obtaining the purified HMG-CoA reductase inhibitor.~~

45. (currently amended) A process for obtaining an HMG-CoA reductase inhibitor according to claim 4 [44], wherein the ~~crude~~ HMG-CoA reductase inhibitor fed onto the chromatography column has an HPLC purity in the range of about 80% to about 95%, and wherein the obtained purified HMG-CoA reductase inhibitor has an HPLC purity of greater than or equal to 99.7% in a pooled fraction.

46. (previously added) A process for obtaining an HMG-CoA reductase inhibitor according to claim 45, wherein the ~~crude~~ HMG-CoA reductase inhibitor fed onto the chromatography column has an HPLC purity in the range of about 85% to about 95%.

47. (previously added) A process for obtaining an HMG-CoA reductase inhibitor according to claim 46, wherein the ~~crude~~ HMG-CoA reductase inhibitor fed onto the chromatography column has an HPLC purity in the range of about 87% to about 95%.

48. (new) A process according to claim 4, wherein the HMG-CoA reductase inhibitor is selected from the group consisting of mevastatin, pravastatin, lovastatin, simvastatin, fluvastatin or atorvastatin.

49. (new) A process according to claim 4, wherein the HMG-CoA reductase inhibitor has a lactone form or is in the form of the acid or the salt thereof.